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Document Management Branch (HFA-305) Docket No. 97N-484S Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

This is to notify the FDA Document Management Branch Docket No. 97N-484S that I have used in the past the allograft from the bone bank and I have used it in numerous patients without any adverse reaction or ill effect. Most of the time, the bone from bone bank, or blood bank, that I have usedconsisted of the femoral shaft. I have also used bone dowel that has been manufactured by the University of Florida in Gainesville, Florida and marketed by Sofamor Danek in the past, again, without any adverse or ill effect. Hopefully, this will clarify some of the issues the FDA may have.

Sincerely,

C. Bhushan, M.D.

Mhuslan, M.D.

CB/st

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